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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 42

Application Number: 08/944,850
Filing Date: October 06, 1997
Appellant(s): WALT ET AL.

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David C. Foster
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed August 22, 2003. This brief is timely filed in reply to the Notification of Non-Compliance With 37 CFR 1.192(c) mailed July 23, 2003.

(0) Citations of Statute

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action (final action of June 20, 2002).

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because the reasons alleged for separate patentability for claim 47 as set forth on pages 9 and 10 of the brief are inadequate because claim 39 anticipates or makes obvious claim 47 (which does not add any step to the recited method and accordingly merely restates what is inherent in clause (d) of claim 39).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

US-5690894-A	PINKEL ET AL.	11-1997
US-5900481-A	LOUGH ET AL.	05-1999

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 39, 40, 43-45, 47, and 48 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Pinkel *et al.* (US005690894A).

In view of the statement under 37 CFR 1.192(c)(7), the explanation of the rejection is applied against independent claim 39.

With respect to independent claim 39, Pinkel *et al.* discloses an assay method corresponding to the disclosed apparatus (Fig. **4**) which comprises a sensor array **14** having at least two subpopulations (the groups of strands **10**) of different sensor elements (sensor ends **11**, where each group may have a different sensor, column 8, lines 50-67). The assay method would comprise the steps of providing the sensor array **14**, adding a sample **30** comprising a first target analyte that binds to the first sensor elements (*e.g.*, first collection **25**), measuring a first fluorescence signal of a first of the first sensor elements **11** and a second fluorescent signal of a second of the first sensor elements **11** (column 13, lines 33-39) with detector **20**, and summing the first fluorescence signals (column 9, lines 12-14 and 21-25).

With respect to dependent claim 47, the Examiner disputes the separate patentability of this claim as stated in section (7) above since the increase in signal-to-noise ratio using the method of

Pinkel *et al.* is inherent in (necessarily follows from) the identity of the apparatus and method of operation.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pinkel *et al.* (US005690894A).

With respect to dependent claim 46, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the baseline of fluorescence signals in the method of Pinkel *et al.* because the detector system may be employed with a computerized data acquisition system and analytical program (column 12, lines 10-22) and such an adjustment (calibration) is a known and useful step in accurately measuring responses.

Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinkel *et al.* (US005690894A) in view of Lough *et al.* (US005900481A).

In view of the statement under 37 CFR 1.192(c)(7), the explanation of the rejection is applied against dependent claim 41.

With respect to dependent claim 41, the sensor elements in the method of Pinkel *et al.* do not comprise beads, but are instead the ends **11** of the fiber strands **10** which may have a specific shape (column 7, line 56 to column 8, line 3). Lough *et al.* shows that beads are known (Fig. **1**) as elements in a sensor array (column 5, lines 62-67). The beads of Lough *et al.* are suitable for the types of binding molecules used and fluorescent signals measured in the sensor array **14** of Pinkel *et al.* and further provide the convex surface Pinkel *et al.* identifies as advantageous. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Pinkel *et al.* to specify that the sensor ends **11** therein were bound to beads as suggested by Lough *et al.* (as the fiber strands **10** in Pinkel *et al.* qualify as a support as described by Lough *et al.* at column 3, line 29).

(11) Response to Argument

There is no issue between the Examiner and Appellant as to whether Pinkel *et al.*, applied under 35 U.S.C. 102(e) as it read at the time of filing, discloses the providing and adding steps recited in clauses (a) and (b) of independent claim 39 to the degree necessary to apply the reference under the statute. Accordingly, the issue is whether Pinkel *et al.* discloses the measuring and summing steps.

Pinkel *et al.* discloses that a single CCD element may be used to detect a signal representing binding of a single species of biological binding partner present at the sensor face **13** of the optical fiber array **14**. See column 12, lines 5-9. In the language of the claim, Pinkel *et al.* shows measuring a fluorescent signal of a first subpopulation of first sensor elements. Pinkel *et al.* also discloses that in the extreme case, the signal for each optical fiber comprising the optical fiber array **14** will be individually focused. See column 11, lines 61-63. Indeed, *individual evaluation of the signal from each fiber or group of fibers* is explicitly taught by Pinkel *et al.* See column 9, lines 16-18. In view of the individual focusing of each optical fiber (in the language of the claim, each sensor element) in a group of strands (in the language of the claim, in a subpopulation) onto a detector which inherently has a plurality of pixels (a known feature of CCDs), measurement of a first fluorescent signal of a first of the first sensor elements occurs in the method of Pinkel *et al.* in a first pixel of the CCD onto which is individually focused the transmission face of a single optical fiber, and measurement of a second fluorescent signal of a second of the first sensor elements occurs in the method of Pinkel *et al.* in a second pixel of the CCD onto which is individually focused the transmission face of another single optical fiber. Accordingly, clause (c) of independent claim 39, the measuring step, is identically shown in the applied reference. While permitting individual evaluation of the signal from each fiber or group of fibers, the method of Pinkel *et al.* uses a single CCD element to detect a signal

representing binding of a single species of biological binding partner present at the sensor face **13** of the optical fiber array **14**, that is, it delivers an aggregate signal representing the subpopulation. See column 12, lines 5-9 again. Since the method of Pinkel *et al.* performs the measuring step of clause (c) as explained above, delivery of an aggregate signal requires the summation of the first and second fluorescent signals measured from the individually focused optical fiber transmission faces. Accordingly, clause (d) of independent claim 39, the summing step, is identically shown in the applied reference.

No modification or combination is required in applying Pinkel *et al.* to dependent claim 46, only the recognition by those skilled in the art that calibration is an ordinary element of a computerized data acquisition system and analytical program. Indeed, Pinkel *et al.* discloses explicitly that the sensitivity, linearity, and dynamic range achievable by a specific combination of optical fiber, sensor face configuration, fluorochrome, excitation and emission bands the like can be determined so as to permit optimization of a given assay format by one skilled in the art (column 14, lines 49-58), keeping in mind that individual evaluation of the signal from each fiber is disclosed. Should the accuracy of the aggregate fluorescence signal be sacrificed to unadjusted variations in sensitivity, linearity, or dynamic range between different fiber strands in a group?

Appellant alleges a silence by the Examiner as to motivation to modify the sensor ends **11** of the fiber strands **10** of Pinkel *et al.* in explaining the combination with Lough *et al.* (page 17 of the brief). From the final rejection mailed June 20, 2002:

> Pinkel *et al.* seeks increased efficiency for the biosensor by an increase in surface area, as by the use of a concave or convex sensor end. It would have been apparent to one skilled in the art that a bead as described by Lough *et al.* provides the ultimate in convexity, and the increased efficiency in the greater surface area provided by a bead would have been entirely sufficient as motivation.

The increase in efficiency through the use of a convex sensor end **11** is described by Pinkel *et al.* at column 7, line 62 to column 8, line 3. Since the word "motivation" was used by the Examiner in rebutting the arguments made in the reply submitted May 20, 2002, the inability of Appellant in over a year to locate the statement does not make for a persuasive argument.

(12) Conclusion

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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Primary Examiner

CH
November 20, 2003

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